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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/392,500	09/09/99	TAYLOR	R 9426-019

020583
PENNIE AND EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK NY 10036-2711

HM12/0206

EXAMINER	
CANELLA, K	
ART UNIT	**PAPER NUMBER**
1642	11

DATE MAILED: 02/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/392,500	Taylor et al
Examiner	**Group Art Unit**
Karen Canella	1642

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3 months* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *20-34, 43-45, and 48-57* is/are pending in the applicat

Of the above, claim(s) *43-45 and 57* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *20-34 and 48-56* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *8*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Acknowledgment is made of applicants election with traverse of Group III, claims 20-34, drawn to methods for detecting cancer comprising the administration of labeled antibody. The traversal is on the grounds that the restriction is improper, that Group II, drawn to antibodies and kits used in the method claims of elected Group III can be examined with Group III without an undue search burden. This is not found persuasive. The antibodies of group II are patentably distinct from the methods of detecting cancer comprising the administration of an antibody, because it can be shown that the antibody as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group II can be used to raise an anti-idiotypic antibody.

For these reasons the restriction requirement is deemed to be proper and is adhered to. The requirement is therefore made FINAL.

2. Claims 1-19, 35-42, 46 and 47 have been canceled. Claims 20-24, 26-34 and 43-45 have been amended. Claims 43-45 and 57, drawn to non-elected inventions, are withdrawn from consideration. Claims 20-34, 48-56 are examined on the merits.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 20-22, 24-27, 29-31, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Morgan (USP 5,376,356). The instant claims are drawn to a method of detecting cancer in a human comprising the administration of a labeled antibody which binds to C3b(i);

waiting for a time interval; detecting the labeled antibody in the subject over background level. Further embodiments include the intravenous administration of a monoclonal antibody which is labeled with a radioisotope and the time interval of 6 to 48 hours. Morgan discloses a method of detecting inflammation in a human comprising the intravenous administration of a labeled monoclonal antibody which binds to C3dg, waiting for a time interval of about 24 hours and detecting the labeled antibody in the subject over background level. The antibody to C3dg will react with C3b(i) since C3b(i) comprises C3dg. Although the object of the invention disclosed by Morgan is the detection of inflammation, the detection of tumors exhibiting C3b(i) is inherent within to said invention.

5. Claims 48, 49, 50 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Morgan (USP 5,376,356). The instant claims are drawn in part to a method of detecting cancer in a human comprising the intravenous administration of an un-labeled IgG or IgM antibody; waiting for a time interval; intravenous administration of a monoclonal antibody which binds to C3b(i); waiting for a time interval; detecting the labeled antibody in the subject over background level. Morgan discloses a method of detecting inflammation in a human comprising the intravenous administration of an unlabeled monoclonal antibody directed against C3dg (column 18, lines 40-51); waiting for a time interval of 30 minutes; administering a labeled monoclonal antibody which binds to C3dg, waiting for a time interval of about 8 hours and detecting the labeled antibody in the subject over background level. The antibody to C3dg will react with C3b(i) since C3b(i) comprises C3dg. Although the object of the invention disclosed by Morgan is the detection of inflammation, the detection of tumors exhibiting C3b(i) is inherent within to said invention.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Morgan (USP 5,376,356) in view of Seya et al (Journal of Immunology, 1990, Vol. 145, pp. 238-245). Claim 54 is drawn in part to a method of detecting cancer in a human comprising the intravenous administration of C3; waiting for a time interval; intravenous administration of a monoclonal antibody which binds to C3b(i); waiting for a time interval; detecting the labeled antibody in the subject over background level. Morgan teaches a method of detecting inflammation in a human comprising the intravenous administration of an unlabeled monoclonal antibody directed against C3dg (column 18, lines 40-51); waiting for a time interval of 30 minutes; administering a labeled monoclonal antibody which binds to C3dg, waiting for a time interval of about 8 hours and detecting the labeled antibody in the subject over background level. Morgan does not teach the administration of C3 prior to the labeled antibody to C3b(i). Seya et al teach that most tumor cell lines do not exhibit more than a slight amount of C-3 deposition. It would have been *prima facia* obvious to one of ordinary skill in the art at the time the claimed invention was made to administer C3 before the administration of an antibody directed to C3b(i). One of ordinary skill in the art

would have been motivated to do so with a reasonable expectation of success by the teachings of Seya et al on the low-level of natural C3 deposition observed in tumor cells.

9. Claims 23, 32, 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morgan (USP 5,376,356) in view of Emery and Harris (Antibody Engineering, 1994). Claims 23 and 32 are drawn to a humanized labeled monoclonal antibody which binds to C3b(i) in the methods of claims 20, 29 and 48-50. Claims 51 and 52 are drawn to a labeled monoclonal antibody of human origin which binds to C3b(i) in the methods of claims 20, 29 and 48-50. Morgan teaches the methods of claims 20, 29 and 48-50 using an antibody of murine origin. Morgan does not teach the methods of claims 20, 29 and 48-50 using a humanized or human labeled antibody directed against C3b(i). Emery and Harris provide general teachings on the use of humanized vs. mouse antibodies or human vs. mouse antibodies in human clinical studies . It would have been *prima facia* obvious to one of ordinary skill in the art at the time the claimed invention was made to use the humanized monoclonal antibody or human monoclonal antibody that specifically binds to C3b(i). One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Emery and Harris on the increased half-life in vivo of the humanized or human antibodies, and the avoidance of human anti-mouse hypersensitivity reactions when using humanized or human antibodies in human clinical protocols.

10. Claims 28, 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morgan (USP 5,376,356) and what is within the purview of one of skill in the art. Claims 28, 55 and 56 are drawn to repeating the methods of claims 20, 48 and 49 at monthly or yearly intervals. Morgan teaches the methods of claims 20, 48 and 49. Morgan does not teach repeating said method at monthly or yearly intervals. Defining the interval of time that is optimum for detecting cancer in an individual is a function of the medical history of said individual and is within the purview of one of skill in the relevant art. It would have been *prima facia* obvious to one of

ordinary skill in the art at the time the claimed invention was made to do repetitive doses on individuals at risk for recurring disease.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

GEETHA P. BANSAL
PRIMARY EXAMINER

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
January 28, 2001